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PSJ14 Janssen Opp Exh 1 – PPLPC051000272272



## **Noramco World Wide Narcotics Franchise**

Overview prepared for the sale of Noramco World Wide Narcotics Franchise global product portfolio including Noramco Wilmington, Tasmanian Alkaloids, and Athens Technical Center



### **Presenters**



#### **Matthew Martin**

#### General Manager

- 32+ Years of industry experience
- Joined Noramco in 2006
- Experience includes CFO, CIO, VP Marketing and Business Unit Leader for several J&J Pharma, Supply Chain and Med Device Companies

#### Anthony Ambrosini

#### WW Controller

- 26 years of industry experience
- Joined Noramco in 2006
- Experience includes Centocor biologics, Nabisco, Avon, and General Chemical

#### Bill Grubb

### **Group Product Director**

- 24 years of industry experience
- Joined Noramco in 1997
- Experience includes development, regulatory, operations, and commercial with J&J and GlaxoSmithKline

## **Important Notice**



Management believes the information provided in this presentation on the narcotic active pharmaceutical ingredients business and related manufacturing operations (the "Business") conducted by Noramco, Inc. ("Noramco") and Tasmanian Alkaloids Pty. Ltd. is accurate and reliable as of the date of this presentation unless another date is indicated. However, neither Noramco nor any of its affiliates in the Johnson & Johnson Family of Companies make any representation or warranty, express or implied, as to the accuracy or completeness of such information. Only those agreements, representations and warranties contained in a definitive written purchase agreement between Noramco and the successful bidder shall have any legal effect. Prospective purchasers are expected to conduct their own due diligence investigation and analysis, and not rely on the information and description of the Business provided herein. In addition, this presentation contains forward-looking statements and information. Neither Noramco nor its affiliates make any representation or warranty, express or implied, as to the accuracy or completeness of such forward-looking statements and information in this presentation. The audience should not rely upon any forward-looking statement or information in this presentation because Noramco and its affiliates give no assurance such statements or information will be realized. Each potential purchaser is expected by Noramco to do its own analysis as to the future prospects of the Business.



# Agenda

	Opportunity and Strategic Rationale	Matthew Martin	4
	Market and Commercial Overview	Bill Grubb	12
18	Manufacturing and Supply Chain	Bill Grubb	26
100	Pipeline	Bill Grubb	39
m	R&D Agricultural and Chemical	Matthew and Bill	45
m	Key Financials	Anthony Ambrosini	58
m	Human Resources	Matthew Martin	62
IIII.	Deal Structure and Timelines	Barry Fitzsimons	66

# **Strategic Rationale For Seller**



Johnson & Johnson is exploring the sale of the Global Narcotics business for the following reasons:

- J&J strategy no longer includes narcotic analgesics
- J&J Pharma supply chain is focused on manufacturing internal products
- Allows J&J to focus on producing novel pharmaceuticals

By focusing on this business from the field to the customer formulation we believe a purchaser can enhance the Noramco value proposition.

# **Opportunity For Purchaser**



Acquire the #1 supplier of Narcotic APIs in the United States, the world's largest market

Gain a global presence with marketing authorizations filed in 30+ countries

Inherit a strong pipeline of new products and filed customer product opportunities

Become a key supplier to the world's largest multi-source generics

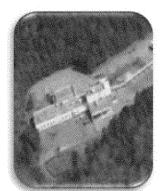
Acquire fully integrated facilities and personnel and external supply network



Wilmington, Delaware
Active Pharmaceutical Ingredients



Westbury, Tasmania Extraction, Ag R&D



Athens, Georgia Building 6
Small Scale Manufacture + R&D

## **Noramco Global Product Portfolio**

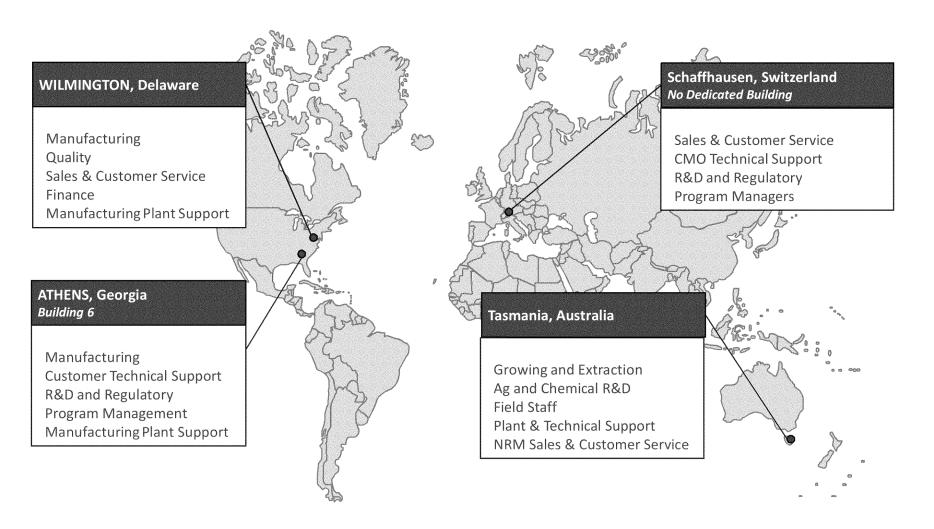


Noramco Family of Active Ingredients	Representative Brand Drug Product	Indication	Net Trade Sales* 2014 in USD MM
Oxycodone	Oxycontin <sup>®</sup> , Percocet <sup>®</sup> , Roxicodone <sup>®</sup>	Pain	\$94
Hydrocodone	Vicodin®, Lortab®	Pain	52
Buprenorphine	Bu-trans®, Norspan® Suboxone®, Subutex®	Pain or addiction	20
Morphine	MS Contin <sup>®</sup> , Embeda <sup>®</sup>	Pain	20
Codeine	Laudanon <sup>®</sup>	Pain	18
Hydromorphone	Dilaudid®, Exalgo®	Pain	9
Naloxone	Narcan <sup>®</sup> , Evzio <sup>®</sup>	Overdose or abuse	2
Other / Intermediates		ADHD and Pain	23
Narcotic Raw Materials			20
Global 2014 Net Trade Sales value			\$258

<sup>\*</sup>Net Trade Sales reflect internal data and are unaudited

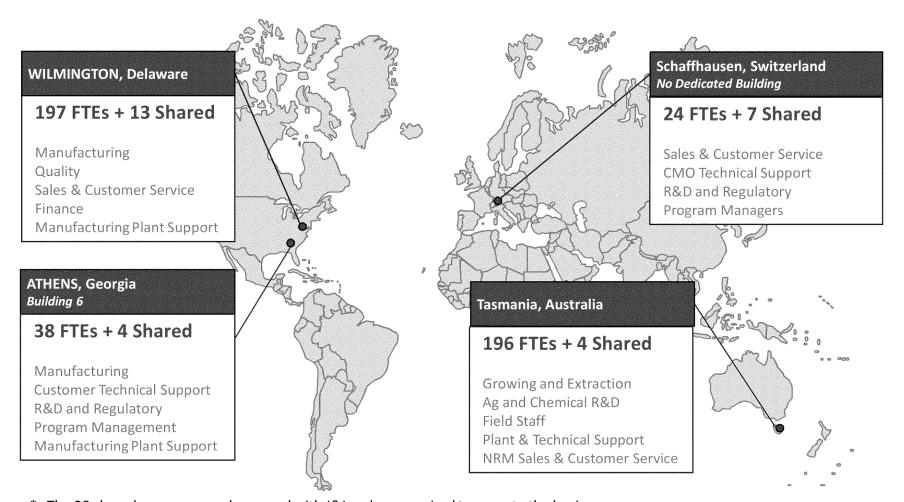
## **Locations and Functions Included in Transaction**





# 483 Full Time Equivalents Support the Franchise (455 direct and 28 shared with J&J\*)





\* The 28 shared resources are leveraged with J&J and are required to operate the business. 2 employees located in UK included within Schaffhausen headcount.

The shared resources <u>are</u> included with Cost of Goods.

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## Products to Be Transferred to Purchaser

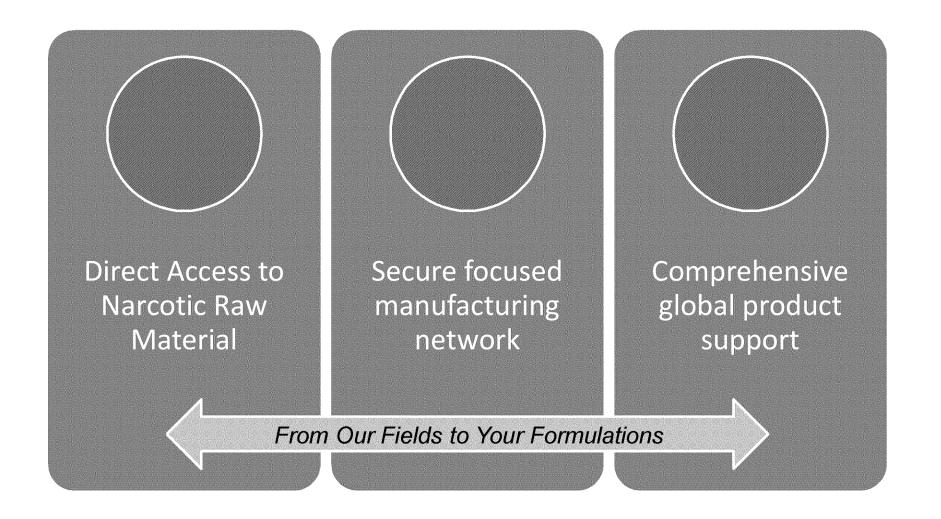
## Transition Supply Agreements are Anticipated



Wilmington	Tasmania	Athens	CMO/Geel/Other
Oxycodone HCl	CPS-Codeine	Hydromorphone HCl	Buprenorphine Base
Hydrocodone Bitartrate	CPS-Oripavine	Buprenorphine Base	Buprenorphine HCl
Morphine sulfate	CPS-Thebaine	Buprenorphine HCl	Codeine Phosphate API
Codeine Phosphate	CPS-Morphine	Methylphenidate HCl	Naloxone HCl
Oxymorphone HCl		Tapentadol HCI	Naltrexone Base
			Naltrexone HCl
			Dronabinol
T-3028 for Tapentadol		Hydrocodone Intermediates	Noroxymorphone
Technical Oxymorphone		Technical Oripavine	Intermediate 5 for Buprenorphine
Technical Thebaine			T-424 for Fentanyl
			T-2955 for Tapentadol
Amphetamine Aspartate		Fentanyl in USA	Methylnaltrexone Bromide (Validation)
Amphetamine Sulfate		,	Oxycodone HCl (Validation)
Dextroamphetamine Saccara	te		Cannabidiol
Dextroamphetamine Sulfate			

# Noramco's Offering







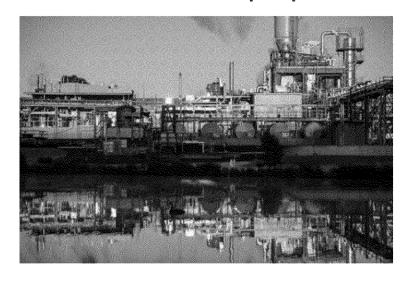
#### Agenda Opportunity and Strategic Rationale Matthew Martin 4 Market and Commercial Overview Bill Grubb 12 Manufacturing and Supply Chain Bill Grubb 26 **Pipeline** Bill Grubb 39 **R&D** Agricultural and Chemical Matthew and Bill 45 **Key Financials** Anthony Ambrosini 58 **Human Resources** Matthew Martin 62 **Deal Structure and Timelines Barry Fitzsimons** 66

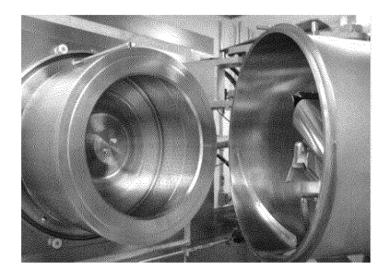
## **The Noramco Story**



#### Our Start...

- Johnson & Johnson formed Noramco 36 years ago for security of supply for Tylenol® with Codeine
- In the mid-80s, J&J acquired Tasmanian Alkaloids, to secure another piece of the value chain
- Noramco since developed processes for and registered a dozen APIs





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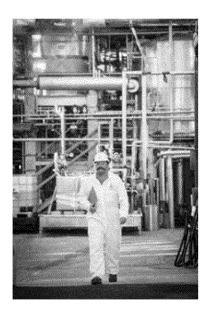
## **The Noramco Story**

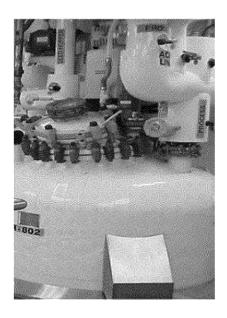


#### Our Focus...

- C-II Controlled Substances: People, Processes, Procedures
- Exceptional support. Over 45 chemists and analysts dedicated to assisting customers to bring their products to market and developing new products
- Compliance. Exemplary FDA, DEA, and EPA compliance records







## **The Noramco Story**



15

### Today...

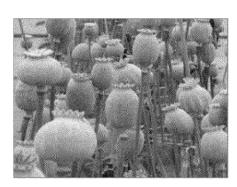
- The largest narcotic API supplier in U.S.
- Focused expansion of synthetic controlled substances for ADD/ADHD
- Rapidly growing ROW footprint for sales and manufacturing
- Exceptional compliance record
- Recognized for superior customer and technical service



## **Franchise Strategy**



- Leverage our vertical integration to deliver the best cost, highest quality, controlled substance APIs
  - Codeine from Tasman poppy
  - Partner with best-cost technology focused manufacturers
- Enter new markets for existing products
  - Target closed markets by supplying API to customers
  - Strategic countries and regions of interest for existing portfolio
- Maintain a leadership position in agricultural R&D
  - Increase alkaloid content to generate capacity and lower costs
  - Breeding programs to assure robust and stable crops
- Participate in growth through partnerships



Focus. Execute. Deliver.

## **Narcotics US & Global Volume Drivers**



- API volume growth linked to expanded use of analgesics driven by aging population and OUS expanded access
- API volume growth linked to generics of Branded drugs, new delivery systems & abuse prevention claims
- No revolutionary new narcotic NRM /API but new uses found
  - Naloxone as a combination for abuse deterrent
  - Methylnaltrexone for constipation
  - Naltrexone for weight loss, drug addiction
- Buprenorphine showing global growth for drug abuse and pain

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# Over 80% of Noramco's Sales are via Long-Term Supply Agreements



Noramco has long-term agreements and/or majority controlled substance share with <u>all</u> 7 of the top US generic companies

Typical supply agreement terms

- Covers multiple controlled substance products (4 or more)
- Agreements are for more than 80% of customer's volume
- Terms are for 3 to 5 years minimum with rolling renewals

Note: Existing agreements are not a guarantee of future business or renewal, purchaser must assess value

# **Key Narcotics Markets are Fully or Partially Closed To the Import of Controlled Substance Narcotics**



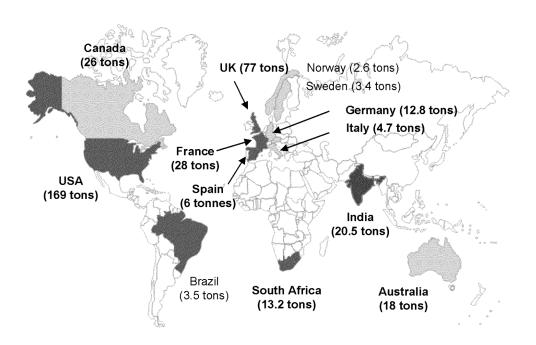


API must be produced in fully closed markets, including the US (the world's largest market)

# Ten Markets Account for 90% of Global Consumption of Narcotic API's



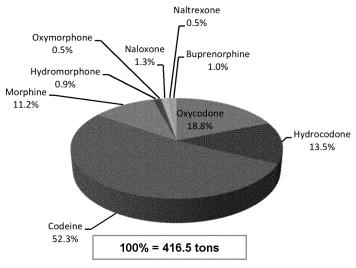
#### **Key Narcotics Consumption by Region**



Source: IMS and INCB 2014

Narcotic APIs includes some narcotic derived API (Naltrexone, Naloxone, etc.)

#### **Global Narcotics Consumption by Volume**



Closed markets (fully or partially)

Narcotic APIs must be manufactured in Closed Markets. Exports are allowed but often have restrictions.

Open Markets

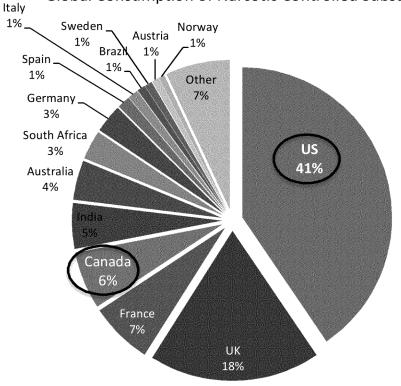
Imports allowed but are highly regulated.

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# North America is 47% of Global Consumption and is <a href="The-Key Controlled Substance Market">The Key Controlled Substance Market</a>







#### North America consumes:

- 82% of the worlds Oxycodone
- 99% of the Hydrocodone
- 99% of the Oxymorphone
- 79% of the Hydromorphone
- 66% of the Buprenorphine
- 61% of the Morphine
- 14% of the Codeine

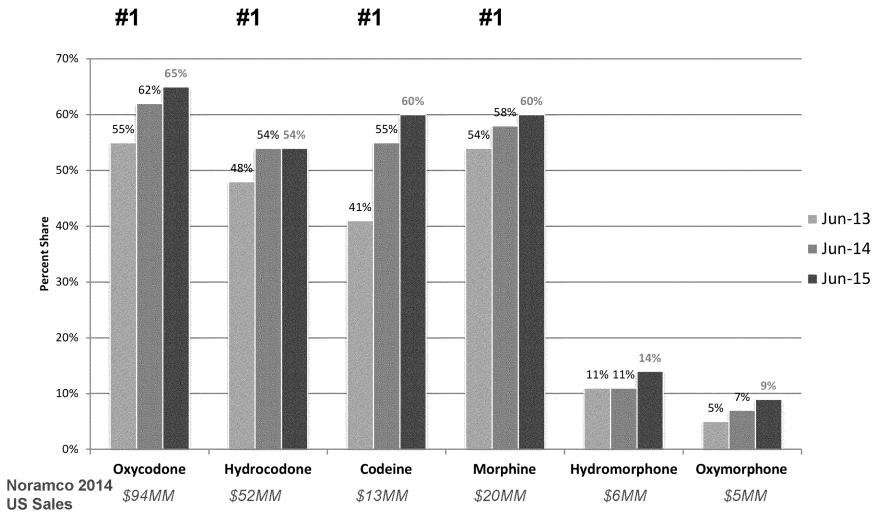
Source: IMS FY 2014

Includes OXY, HBT, CPH, PMS, OMH, HMH, NLX, NTX, BUP.

Excludes synthetics and ADHD/ADD drugs

# **Noramco Has Steadily Gained US Market Share**





Source for Share: IMS sales data,

Source for Noramco US sales: unaudited company financials

# **Competitive Landscape**



Noramco Has A Focused API Portfolio Backed By Secure Internal Supply Of Narcotic Raw Material

	Focus Area	Narcotic Raw Material Capability	Primary Markets
Noramco	API Supplier to Largest Generics	Major Supplier	Global NRM and API
Mallinckrodt	Branded dosage	No	Primarily US
Rhodes Tech	Internally focused API for Purdue	No	Primarily US
J. Matthey	CRO and CMO and FDF	Limited	Global
Francopia	Brand and Generic API	Yes	Primarily OUS
Siegfried	CMO and FDF	No	Global
Cambrex	CMO and Generic API	No	Global
Alcaliber	NRM supplier limited API	Yes	OUS
Others	Sun, Aspen, AMRI	Varies	Varies

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## **Narcotics Global Trends And Future**



### **Global Market Past**

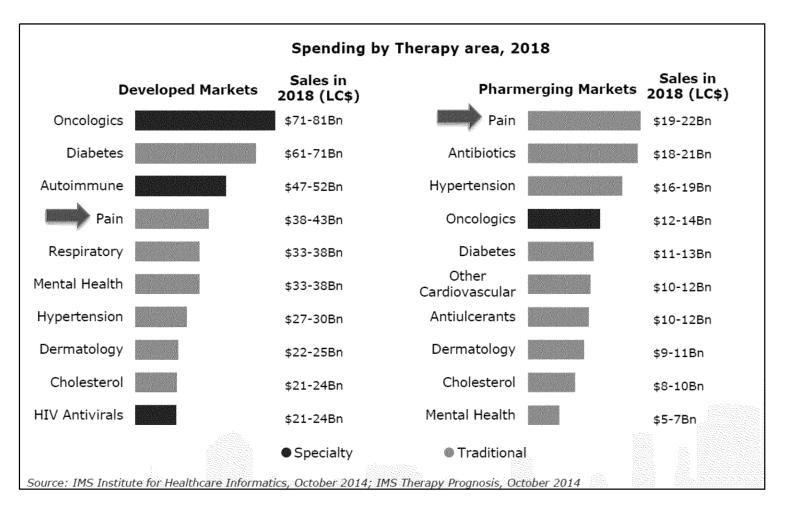
- Codeine and Morphine primarily used for analgesics OUS
- Enforcement reduced market size by ~2% per year from 2011 to end of 2014, appears to be stabilizing
- Stronger analgesics (Oxycodone, Hydromorphone, Oxymorphone) reformulated for Extended Release presentations

### **Global Market Future Trends**

- Aging population and increasing wealth increase analgesic demand
- Stronger analgesics in Abuse
   Deterrent presentations will gain
   more acceptance in new markets
- US Multinationals will continue to expand pain franchises OUS with Generics and Branded Generics

# Pain Finished Dose Sales Are Projected To Increase To \$57 To \$65 Billion By 2018





Today Pain Is The Number One Therapy Area For Generics Both In Value And Volume In Pharmerging Markets

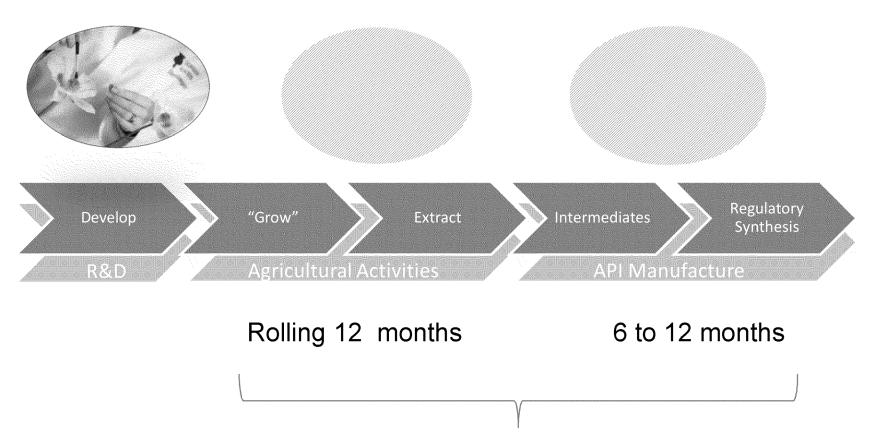


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# **Fully Integrated Supply Chain Provides Security**



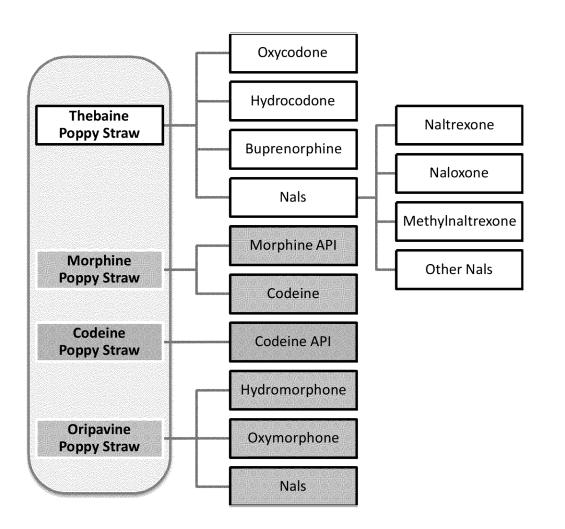


## Generally Field to Formulation is 2 years

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# Narcotic Raw Material Is A Critical Foundation In A Complex Supply Chain



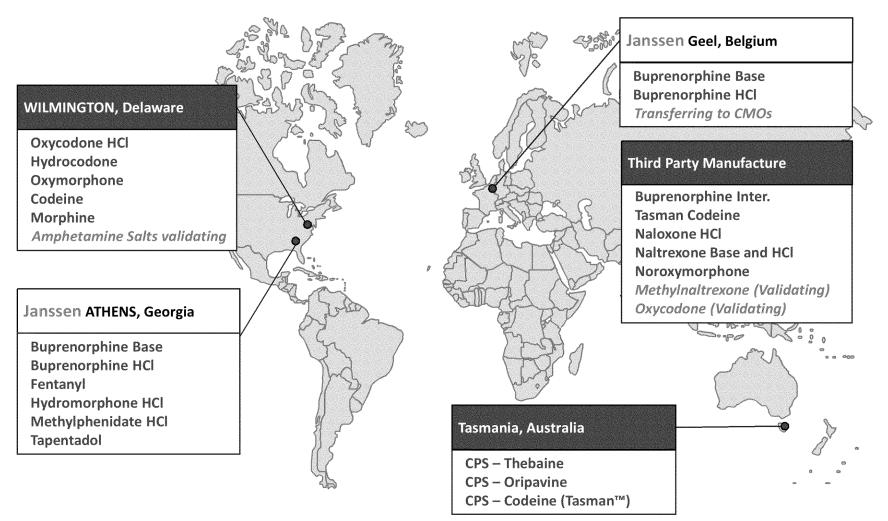


- Tasmanian Alkaloids produces over 40% of the world's supply of Narcotic Raw Materials
- Tasmanian Alkaloids has the highest content poppies for key alkaloids
- Many APIs may be made via different routes of synthesis

INCB report issued March 2015 notes that Tasmania produces 77% of the World thebaine

# **Noramco Manufacturing Network**





Note: This is a summary, not intended to show all office relationships

# **Excellent Compliance: Quality**



#### **Tasmania**

- Most recent FDA inspection was February 2013
- No Form 483 was issued

#### Wilmington

- Most recent FDA inspection was November 2014
- No Form 483 was issued
- Over 5 years since the last inspection in which a From 483 was issued

### **Athens Total Site**

- Most Recent FDA inspection was February 2014
- No Form 483 was issued.
- There has never been a Form 483 related to any part of API or intermediate manufacturing in Athens

Noramco and Tasmanian Alkaloids host customer audits by the world's largest brand and multisource generics routinely

## **Excellent Compliance: DEA**



### Wilmington

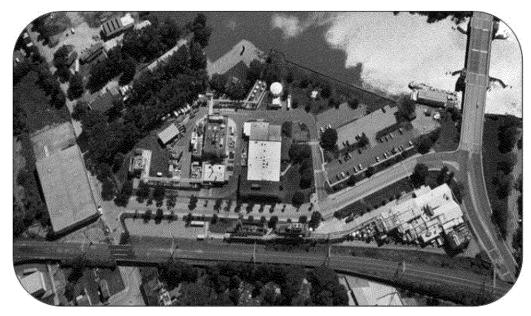
- Most recent DEA inspection was July and August 2015
- 5 week inspection with zero observations based on the review of prior three years of transactions

## Athens (total site)

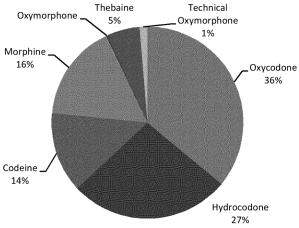
- July 2015 DEA inspection of Importer registration zero observations
- Most recent manufacturing inspection was 2013

## Noramco, Wilmington, DE





750+ tons per year Finished API and Intermediates



Key Products % by Kgs produced

#### **Facility Size:**

- 81,000 sq ft.
- 140 m3 reactor capacity

#### Other:

- Approximately 30 minutes from Philadelphia Airport
- Located on Wilmington, DE waterfront

#### **People Total 197**

177 Supply Chain Personnel

- 24 hrs x 7 days
- · Non-Union Site

20 Off-Site Business Personnel

 Sales, Customer Service, Finance, Logistics

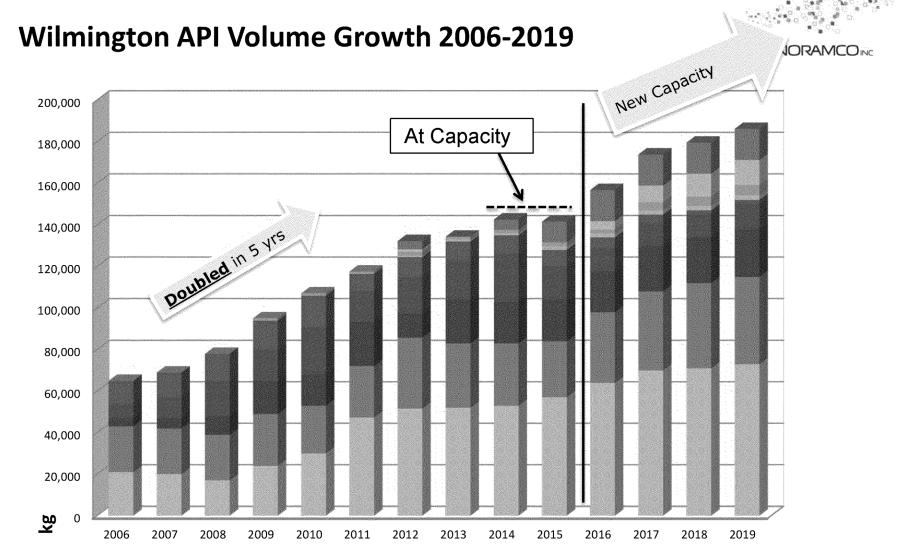
#### **Capabilities**

- Over 750,000 Kg/year produced
- · GMP chemical processing
- · DEA secure manufacturing
- Multiple Vaults
- Hydrogenation Chemistry
- 1,100 to 10,500 L Reactors
- Multiple dryer technologies
- · Milling & Custom Packaging

#### **Regulatory Profile**

- FDA, EDQM, DEA, EPA, OSHA, Health Canada, Homeland Security
- Multiple customer audits monthly
- Active US Foreign Trade Zone

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- Oxycodone HCl
- Morphine Sulfate
- Oxymorphone, crude (COMd)
- Hydrocodone Bitartrate
- Technical Thebaine
- Amphetamines

- **■** Codeine Phosphate
- Oxymorphone HCl
- Tapentadol Intermediate

# Recent Wilmington Investments Provide Capacity And Support Growth



Hydrogenation capacity Complete
 Doubled capacity for Oxycodone and Oxymorphone

Drying capacity

New 2000L dryer Complete
New 1000L dryer Complete

Milling capacity\$14 MM expansion

Completion 2016

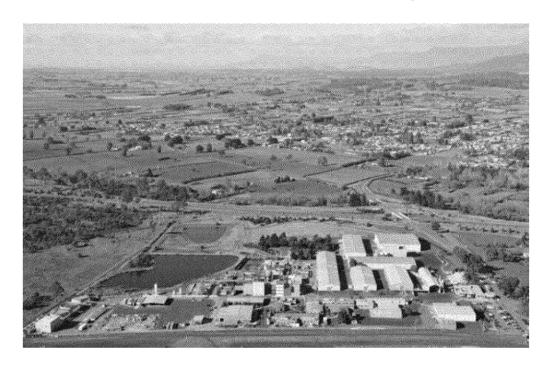
Focused Factory
 Hydrocodone, Codeine, Morphine

*In progress 2015 / 2016* 

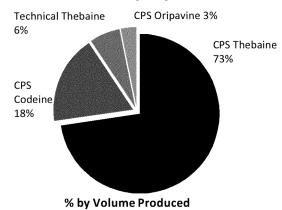
These investments **provide capacity** and room for expansion

## Tasmanian Alkaloids, Westbury, Tasmania





#### 300 tons per year



#### **Key Products**

- Concentrate of Poppy Straw (CPS)
   Thebaine, Codeine, & Oripavine
- Technical Thebaine
- Poppy Seed (Raw Agricultural Commodity)

**Facility Size:** 128,718 sq.ft. 148 m3 reactor capacity

People: 200 Total

Site 24 hrs x 7 days

#### Capabilities

- 300 tons per annum extraction capacity
- Modern Drying and Packaging
- Spent biomass Solvent Removal

#### **Regulatory Profile**

 FDA, TGA, PMDA, Health Canada, EDQM, DEA, INCB, Australian Federal and State Government Authorities

### **Delivery Model**

Ag R&D Growing Harvesting

Agriculture Advising

Extraction

Distribution







# Security of Supply: Raw Material From Tasmanian Alkaloids to Noramco

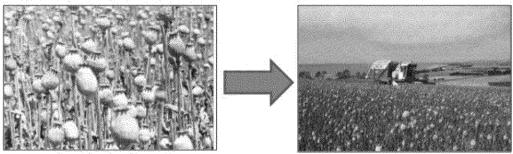






Poppies in Flower

Green Poppies



Ready for Harvest

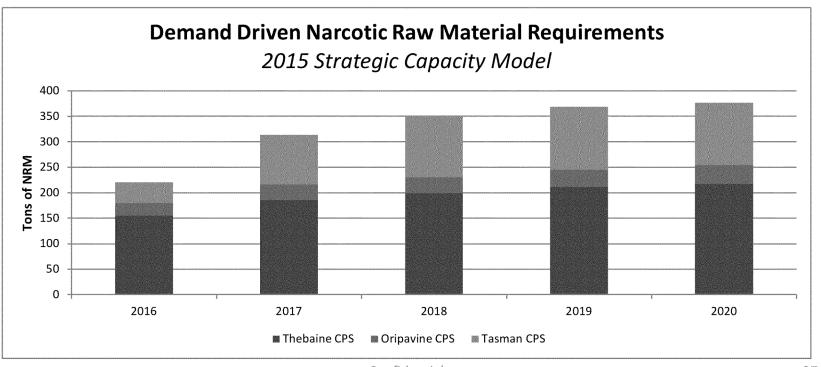
Harvesting



# Tasmanian Alkaloids Recent Investment of \$27 MM Increased Capacity by 50%

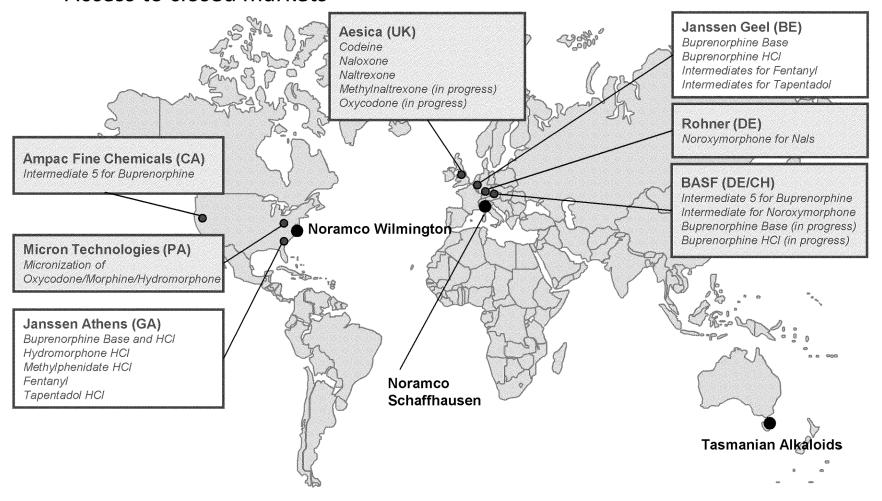


- 300 tons per annum capacity at Tasmanian Alkaloids
- 3<sup>rd</sup> party contract extractor <u>demonstrated and qualified</u>
  - Utilize contract extraction above 300 tons (no capital expenditure)
  - Annual increase in poppy content will boost capacity



# Noramco's Established External Manufacturing Network

- W NORAMCO<sub>INC</sub>
- Efficient access to specialized equipment and technology
- Access to closed markets



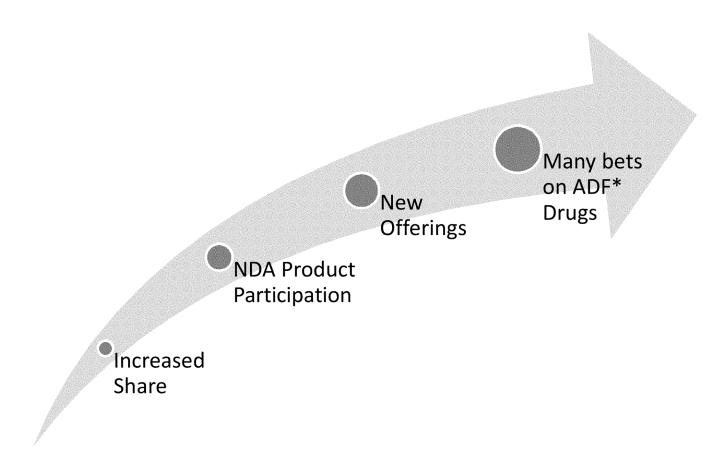


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# **Noramco Growth Drivers and Upside**





<sup>\*</sup> ADF = Abuse Deterrent Drug Formulations

#### **Growth in Noramco Share is Possible**

393025

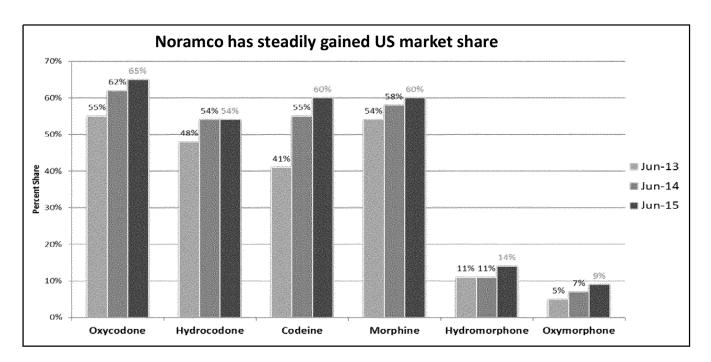
New Offerings

NDA Product
Participation

Increased
Share

Growth in share supported by contracts with key finished dose providers\*

- Completed qualifications (oxymorphone)
- Customer qualifications that are in-progress (hydromorphone)
- Capitalizing on key brand to generic switches (Oxycontin)



<sup>\*</sup> Existing contracts are not a guarantee of future business

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# **Customer NDA Product Launches Where Noramco Supplies API**



Noramco API	Methylnaltrexone	Buprenorphine HCl	Naltrexone HCl	Oxycodone NME
Company	Confidential	Confidential (two)	Confidential	Confidential
Product	Relistor	Sub-Q NDA Formulations	Contrave®	NKTR-181 Peg-Oxy
Indication	Opioid-Induced Constipation (OIC)	Opioid Addiction	Obesity	NME: Pegylated Oxycodone
Status	Submitted NDA June 23, 2015	Commercial and & Ph II NDA	Partnering to resolve formulation issues	Enrolling Ph III complete by YE 2012
Expected Noramco Commercial Approval	1H 2017	Confidential ercial, d 2016 to 2018	Commercial, Noramco potential in 2017/18	1H 2018
Notes	Long-term supply agreement for supply of >75% of Methylnaltrexone. Supplying 1.8tons in next 18 months	Several NDA and NDA, 505(b)2 opportunities not listed	FDA agreed in Oct to a faster path to resubmitting NDA; enrolling in last clinical ahead of schedule	Noramco selected as second source, development agreement drafted. Post approval submission



# **New Offering (Pipeline) from Noramco**



Noramco API	Cannabinoid Family	Amphetamines	Fentanyl
Company	Confidential	Confidential	Confidential
Product	Epidiolex® and Sativex® and their generics	Generics of Adderall®, Dexedrine®	Generics of Duragesic®, Actiq®
Indication	CNS, Seizure, Pain	ADHD	Pain
Status	Clinical material using Noramco IP. Purchase Order in hand	Q1 2016 Filing Launch 2017/2018	Filing submitted Feb 2015, assessing customer interest with samples
Market Comment	Confidential Estimate 10 to 50 tons	Current US Market ~26 tons, growing at 11%	US Market ~1,200kg

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# Working With Innovators Assures Noramco Participates In ADF\* Launches

393028	Many Bets
	NEW Offerings Oracle  NDA Product Participation
Increased Share	

Product	Active	ADF Means	Noramco	Status
	Oxycodone	Antagonist (NIC)	100%	Commercial
	Morphine	Antagonist (NTX)	100%	Commercial
	Hydromorphone	Mechanical	100%	Commercial
	Tapentadol	Mechanical	100%	Commercial
	Oxymorphone	Mechanical	80%	Commercial
	Oxycodone	Antagonist (NTX)	100%	Commercial
	Oxycodone	Mechanical	10%	Commercial
Confidential	Oxycodone	Mechanical	Mallinckrodt	Commercial
[en	Hydrocodone	Mechanical	100%	Commercial
] Jijia	Hydrocodone	Antagonist (NTX)	100%	Development
	Oxycodone	Mechanical	100%	Development
	NME: Peg-OXY	Biochemical	In Progress	Development
	NME: Prodrug	Enzymatic	In Progress	Development
	Codeine	Mechanical	100%	Filed
	Hydromorphone	Antagonist (NLX)	100%	Filed
	Oxycodone	Mechanical	100%	Filed
	Oxycodone	Antagonist (NLX)	10%	Filed
Tener encontrol control and a second control control control and a second control cont	Morphine	Mechanical	90%	Filed

- Noramco is the sole supplier to the vast majority of commercial and ADF formulations
- Included in filings because we could meet requirements nobody else could (or would)

\*ADF= Abuse Deterrent Drug Formulations



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•	Key Financials	Anthony Ambrosini	58
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100	Deal Structure and Timelines	Barry Fitzsimons	66

# **Creating A Sustainable Competitive Advantage And Achieving The Lowest Cost**

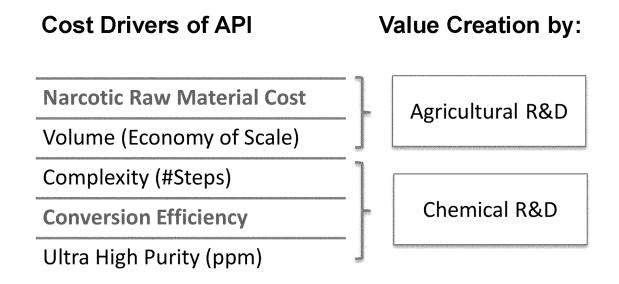


# Narcotic Raw Material Cost Volume (Economy of Scale) Complexity (#Steps) Conversion Efficiency Ultra High Purity (ppm) Value Creation by: Agricultural R&D Chemical R&D

# **Creating A Sustainable Competitive Advantage And Achieving The Lowest Cost**

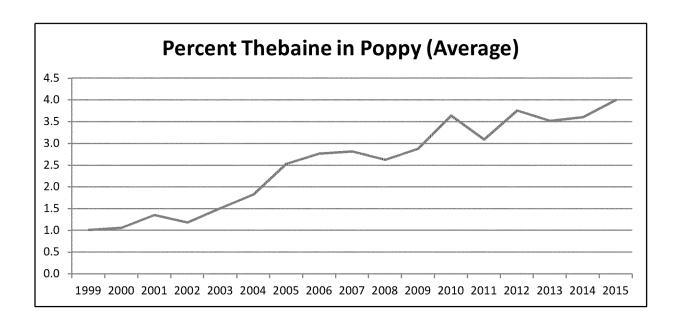


All are important but....



## The Value of Agricultural Research





- Narcotic raw material is the single biggest contributor to API costs
- Tasmanian Alkaloids has increased the alkaloid content by 300% over the last 15 years
- INCB data validate that these increases are unparalleled in the industry

## **Current Ag R&D Objectives**



- Increased yield (alkaloids per ha)
- Reduced processing costs (reduce crop: straw ratio, capsule characteristics)
- Increased crop production efficiency to reduce the gap between average and maximum crop yields
- Risk management of raw material supply (new production regions e.g. Victoria)

#### Tasmanian Alkaloids R&D - Three Areas of Work



- Plant Breeding and Improvement
  - On-going core activity that has delivered results
- Agronomy
  - Translating Agricultural R&D to the field
  - Leveraging Field Staff
- Biotechnology
  - Transformational innovation area

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## Plant Improvement – In Tasmania



#### **Description**

Ongoing conventional plant breeding program to improve the alkaloid content and productivity

#### **Objective**

Release new varieties with 5% increase per year relative to previous year

#### **Desired Outcomes**

Increased Thebaine and Codeine yields per ha

Improved growth characteristics (e.g., constant height, dwarf varieties, etc)

Production of thebaine and codeine lines with differential herbicide resistance (decreased field and factory production costs)

Development of seedless or sterile varieties (increased straw/crop ratio)

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## **Agronomic Research**



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#### **Description**

Increase poppy plant production efficiency and alkaloid yield production through optimisation of crop husbandry (i.e., R&D translated to the real world with field staff)

#### **Objectives**

Introduction of new technologies to increase crop production efficiency and decrease field and processing costs

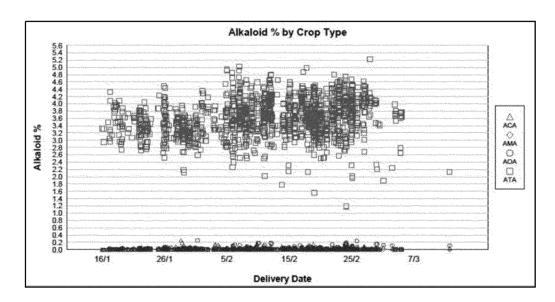
#### **Desired Outcomes**

Reduction in gap between average and best yields

Increase yields per ha

Increase disease resistance

Improve growth characteristics



## Biotechnology – In Tasmania



#### **Description**

Develop poppy polyploids for commercial crop production using targeted mutagenesis and gene regulation

#### **Objectives**

Increase efficiency of alkaloid production

#### **Desired Outcomes**

Increase Thebaine and Codeine alkaloid content from current level by 20% in the near term and 50%+ long-term

Development of seedless or sterile commercial varieties

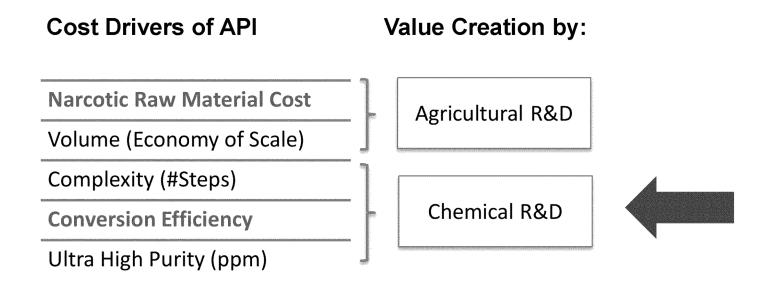
Provide new parent material for conventional breeding

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# **Creating A Sustainable Competitive Advantage And Achieving The Lowest Cost**



All are important but....



## **Chemical and Analytical R&D Summary**



- Tasmanian, Australia
  - Extraction improvements and development on all poppy varieties
  - Extraction support and process troubleshooting (including external API's)
- Athens, Georgia and Wilmington, Delaware
  - Customer support and specialized customer samples
  - Plant support for Noramco manufactured API's and US external intermediates
  - Development and improvements of new and existing API's + reference standards
- Schaffhausen, Switzerland
  - Development and improvement of API and intermediate processes
  - Production Support of all externally manufactured API's
- Global Functions Located Across Sites:
  - Regulatory Affairs and Technical Services

## **Summary of Key Chemical R&D Contributions**



## Developed and commercialized 10+ APIs in 6 years

## Cost of goods improvements for core products

(oxycodone, hydrocodone, codeine, morphine, Nals, and Bup)

- 2015 is a transition year for customers to new Oxycodone and Codeine processes
- Full-year benefit to COGS in 2016 for >75% of Oxycodone volume and >50% of Codeine

## Fully filed dual-sourced Nal-family via thebaine or oripavine

## R&D has adapted our products to secure business

- Inclusion in ADF forms by low level impurity control
- New filed particle sizes for sophisticated ER formulations

## **Schaffhausen Business and Technical Operations**



#### World Wide Narcotics Franchise Schaffhausen:

- Manages virtual OUS Supply Chain with products representing 50% of NF product portfolio, approx 15 SKUs
- Owns and maintains IP of the Naltrexone family APIs including regulatory filings
- Profits from Swiss tax benefits
- Very experienced and productive R&D center for WWNF
- Developing a commercial process for the new API Cannabidiol
- Overall HC of 30 (8 within JSC)

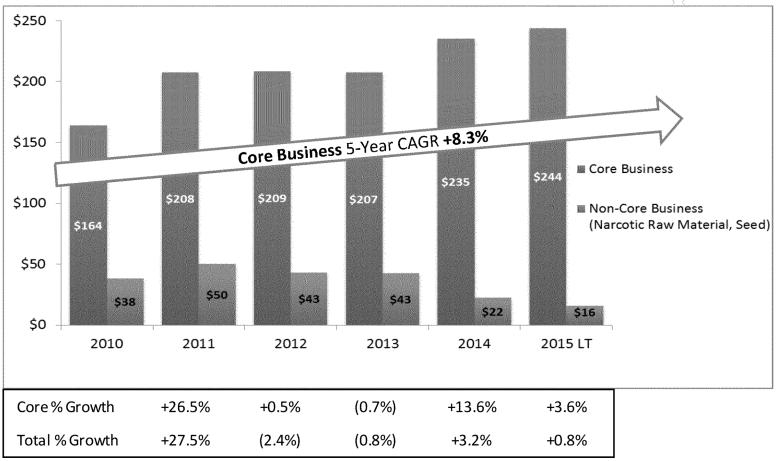


A٤	Agenda							
ш	Opportunity and Strategic Rationale	Matthew Martin	4					
ш	Market and Commercial Overview	Bill Grubb	12					
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# 2010 – 2015 Noramco Sales (\$MM, Unaudited)



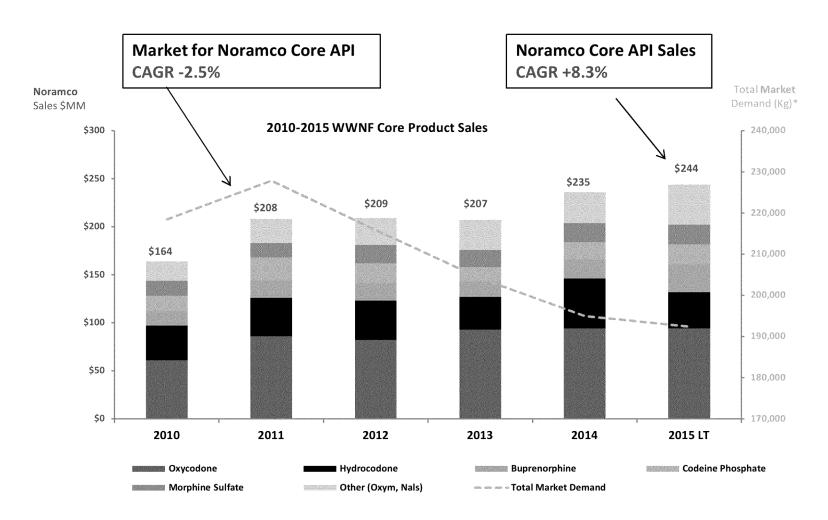


- Core Business sales continues to grow due to increase in market share
- Total Noramco sales 5-year CAGR of +5.1% (Core Business is +8.3%)

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# Noramco Core API sales have increased in a declining market (Unaudited)

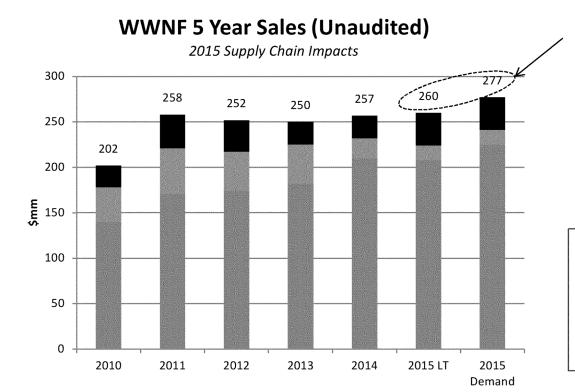




<sup>\*</sup> Total Market Volume includes IMS sales actuals through June 2015 in markets accounting for >92% of Noramco Sales

# **WW Narcotics: Supply Chain Impacts to 2015 Sales**





■ US ■ NRM ■ OUS API

Customer Demand Exceeds Supply by \$17mm

Supply issues example:

25% of Oxycodone produced this year has been reprocessed

Impact: 2015 US Sales would be 6 to 10% higher without Supply Issues

# 2010 – 2015 Noramco Financial Metrics (\$MM, Unaudited)



												> (
	2	2010	2	2011	2	2012	2	013	2	2014	20	15 LT
Revenue	\$	202	\$	258	\$	252	\$	250	\$	258	\$	260
Cost of Products Sold		(138)		(172)		(176)		(180)		(180)		(188)
Gross Profit GP %	\$	<b>64</b> 32%	\$	<b>86</b> 33%	\$	<b>76</b> 30%	\$	<b>69</b> 28%	\$	<b>78</b> 30%	\$	<b>71</b> 28%
SG&A		12		11		14		17		15		14
R&D		11		9		11		12		14		14
Total Operating Expense	\$	23	\$	20	\$	25	\$	29	\$	29	\$	28
Expense % to Sales		11%		8%		10%		12%		11%		11%
Other Expense/(Income)		1		1		2		(2)		(1)		(1)
Operating Income	\$	40	\$	65	\$	49	\$	42	\$	50	\$	45
Operating Margin %		20%		25%		19%		17%		19%		17%
Depreciation		19		18		16		15		16		16
Amortization		-		-		-		-		-		-
EBITDA	\$	59	\$	83	\$	65	\$	58	\$	66	\$	61
% to Sales		29%		32%		26%		23%		25%		23%
Financial Metrics									· ·			
Cash Flow	\$	28	\$	21	\$	(2)	\$	(14)	\$	2	\$	20
Inventory	\$	120	\$	122	\$	154	\$	203	\$	223	\$	229
Capital Spend	\$	15	\$	21	\$	20	\$	25	\$	23	\$	19

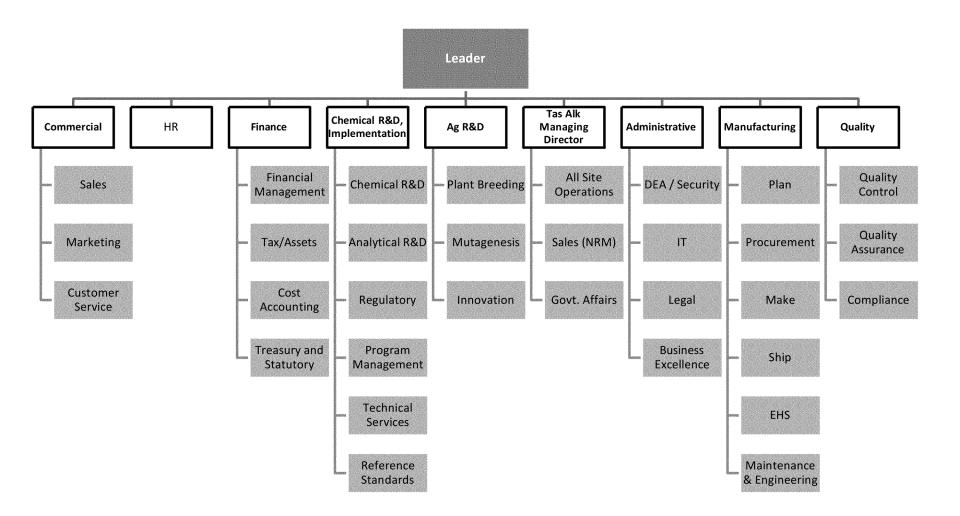
Note: The 2013 and 2014 financial information above excludes inventory reserves of \$19MM and \$11MM, respectively, where that inventory is expected to be sold through in 2016 or beyond.



A	Agenda						
18	Opportunity and Strategic Rationale	Matthew Martin	4				
102	Market and Commercial Overview	Bill Grubb	12				
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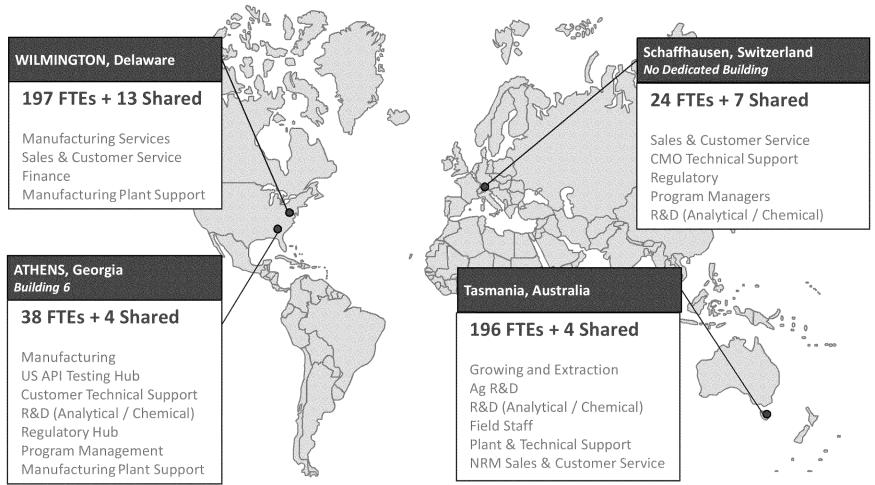
## **Noramco Organization**





# 483 Full Time Equivalents Support the Franchise (455 direct and 28 shared with J&J\*)





The 28 shared resources are leveraged with J&J and are required to operate the business.

The shared resources <u>are</u> included with Cost of Goods.

<sup>2</sup> employees located in UK included within Schaffhausen headcount.

#### **Human Resources Considerations**



- Transfer of 455 FTE to buyer
- Maintain comparable level of compensation for at least two years
- J&J has implemented retention bonuses to key employees to ensure business continuity



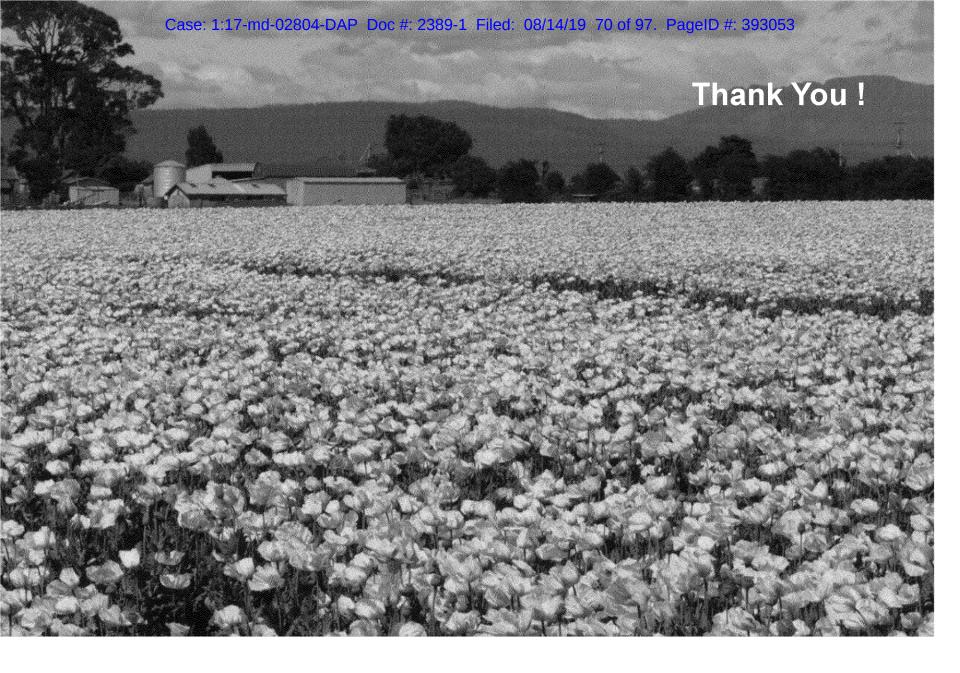
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#### **Deal Process**



- After management presentation, process letter for preliminary bid sent to you describing
  - Cash consideration for business
  - Source of financing and need for audited financials
  - Indication of level of review and approval within organization prior to submission of preliminary bid
- Data room access based on preliminary bid
- Submission of final binding bids
- Contract negotiations

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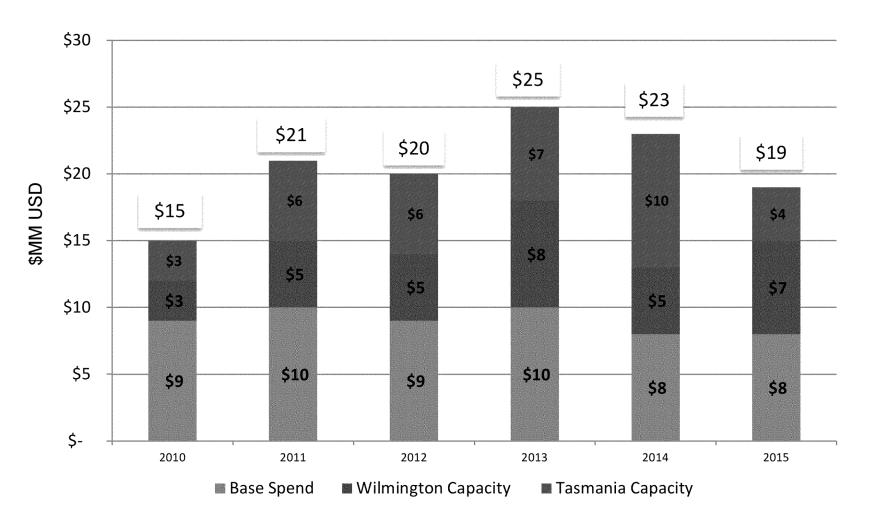
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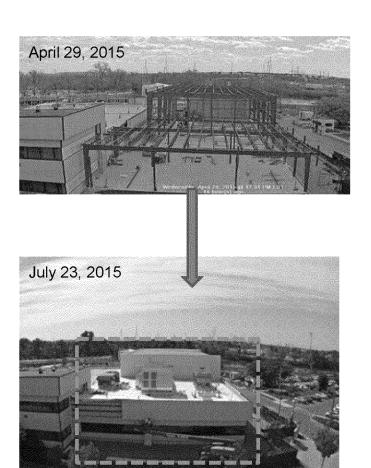
# Noramco 2010 – 2015 Capital Spend





# Increased Capacity Wilmington: \$14 MM Expansion Underway





- Fully approved and in progress
- Warehouse vault and office occupancy Nov 2015
- Milling on-line Q1 2016
  - Doubles the milling capacity of all products (currently a bottleneck)

## **Global Regulatory Portfolio**



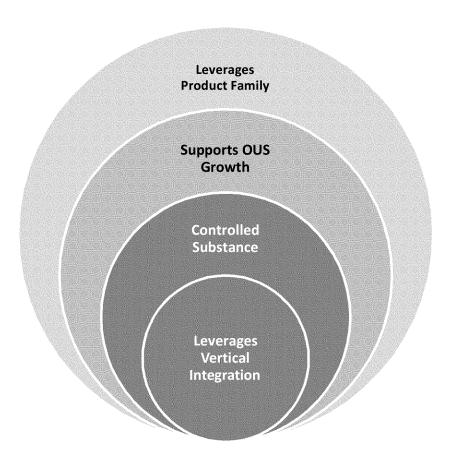
Current Dossiers											
Product	Mfg. Site	USA	Canada	ерам сер	Japan	Australia	New Zealand	EU/ROW			
Amphetamines (4 DMFs)	WΤ	*									
	Tas Alk	Т	Т	Т	Т			Т			
Buprenorphine Base	Geel	N	N	N	*	J	J	J			
	AT	N									
Burranarahina HCI	Geel	N		N		N		J			
Buprenorphine HCI	AT	N	*								
Cadaina Dhaanhata (alaasia)	Tas Alk			Т				Т			
Codeine Phosphate (classic)	WT	N									
WT WT	WT	N									
Codeine Phosphate (Tasman)	Aesica			N				N			
Dronabinol	Cilag	С									
Fentanyl Base	AT	N	*								
Hydrocodone Bitartrate (nHBT)	AT/WT	N	N								
Hydromorphone HCI	АТ	N	N	N		N	N	J			
Iron Sucrose	Cilag	С						С			
Methylnaltrexone Br	Cilag	С									
Methylphenidate HCl (current)	АТ	N	N	J	J	J	J	J			
Methylphenidate HCl (one-step)	АТ	*	*	*							
Morphine Sulfate	WT	N	N								
Naloxone HCI	Cil/Aesica	С	С	С				Closed			
Naltrexone Base	Cil/Aesica	С						*			
Naltrexone HCI	Cilag	С		С				С			
Oxycodone HCI (nOXY/OXY3)	AT/WT	N	N	N		N	N	N			
Oxycodone HCI (OXY3)	Aesica			N							
Oxymorphone Base	WT/AT	N (IND)									
Oxymorphone HCI	WT	N									
Purified Oxycodone Base	WT	N	*								

\*In-process
N=DMFs held by Noramco
J=DMFs held by J&J
T=DMFs held by TasAlk
C=DMFs held by Cilag

## **Noramco Product Strategy Summary**



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Leveraging Narcotic Raw Materials from Tasmania

Controlled Substance Agonist or Antagonist

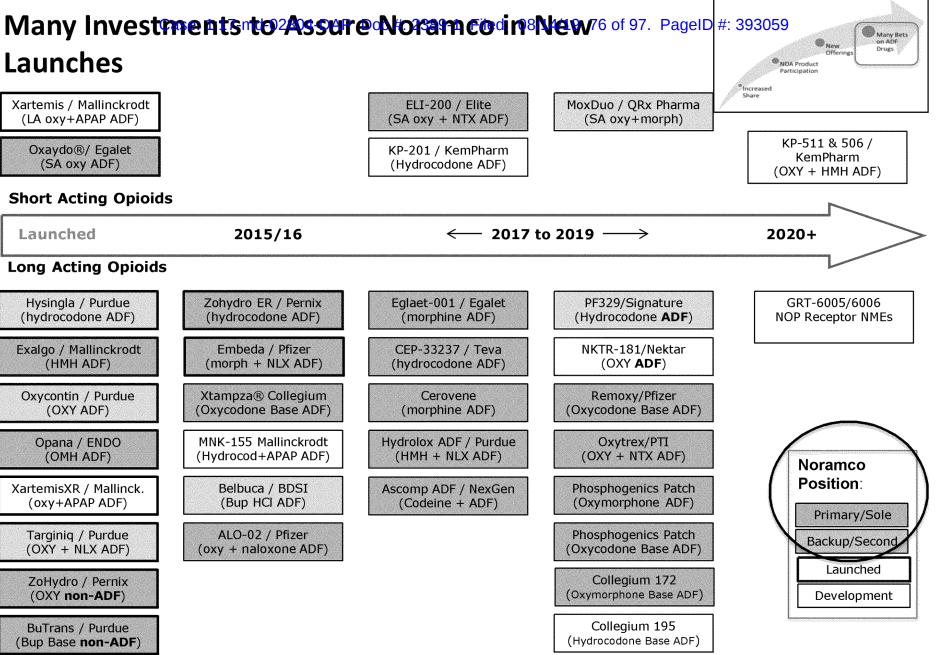
Sustainable Competitive Advantage

## **Current Facilities and Offices**



•	USA	Personnel Supporting Business
	Wilmington DE Manufacturing Site	174
	Leased Office Space Wilmington	21
	Athens GA Research and Office Space	56
•	Switzerland Office and Laboratory Space	30
•	Tasmania Westbury Manufacturing Site	200
•	UK 2 Home Based Offices	2 ~483 Total

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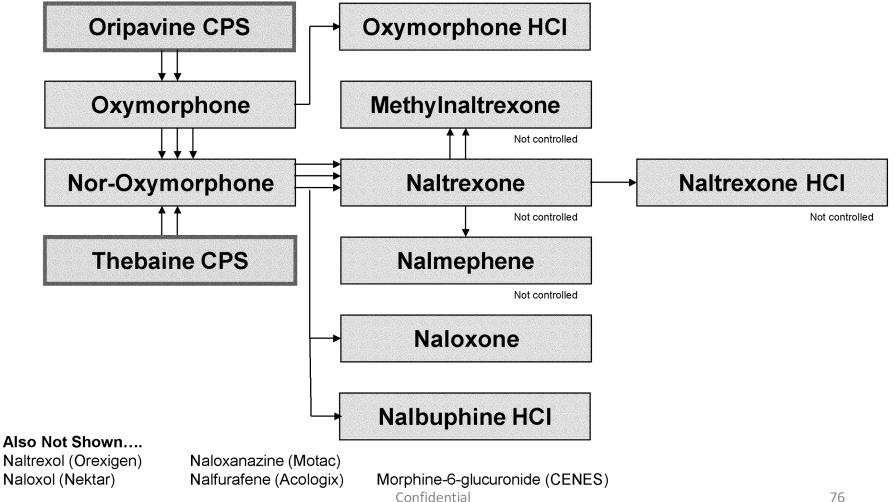


ADF = Abuse Deterrent Formulation

<u>Source</u>: BioMed Tracker, IPD Analytics, company websites & investor relations calls Confidential
Generic estimates based on patent exclusivity expiration date in "FDA Orange Book" or litigation settlements. Noramco Product Management

## The Nal-Family





## The Value of Chemical R&D



### Oxycodone API

- Conversion efficiency increased by 10%
- Overall right-first-time in production increased by 5%
- Plant occupancy reduced by 25%

Standard costs **reduced by 7%** from 2013 to 2015

### Tasman Codeine API

- Reduced manufacturing steps by 60%
- Eliminated reliance on Turkey
- Leveraged Tasmanian
   Alkaloids

Standard costs reduced by 36% from 2013 to 2015



## **Groundhog: Supplemental Information**

October 21, 2015



## **Important Notice**



Management believes the information provided in this presentation on the narcotic active pharmaceutical ingredients business and related manufacturing operations (the "Business") conducted by Noramco, Inc. ("Noramco") and Tasmanian Alkaloids Pty. Ltd. is accurate and reliable as of the date of this presentation unless another date is indicated. However, neither Noramco nor any of its affiliates in the Johnson & Johnson Family of Companies make any representation or warranty, express or implied, as to the accuracy or completeness of such information. Only those agreements, representations and warranties contained in a definitive written purchase agreement between Noramco and the successful bidder shall have any legal effect. Prospective purchasers are expected to conduct their own due diligence investigation and analysis, and not rely on the information and description of the Business provided herein. In addition, this presentation contains forward-looking statements and information. Neither Noramco nor its affiliates make any representation or warranty, express or implied, as to the accuracy or completeness of such forward-looking statements and information in this presentation. The audience should not rely upon any forward-looking statement or information in this presentation because Noramco and its affiliates give no assurance such statements or information will be realized. Each potential purchaser is expected by Noramco to do its own analysis as to the future prospects of the Business.

## **Supplemental Content**



#### Financial

- Detail 1: Product Revenue Split by Geography by Product Family
- Detail 2: Materials Supplied to J&J Affiliates
- Detail 3: Inventory By Product and Region
- Detail 4: SG&A Detail by Year
- Detail 5: Value of Improvements to Oxycodone and Codeine

#### Scope of Sale Information

- Detail 6: Product Transitions Needed and Draft Timeline
- Detail 7: Volumes For Capacity Analysis
- Detail 8: Headcount by Function by Site

#### Tasmanian Alkaloids Information:

- Detail 9: Tasmania land area grown split by TasAlk and GSK
- Detail 10: Alkaloid content detail for thebaine and codeine

## Detail 1: Revenue by Product by Region

(\$mm, Un-audited)



	2010	2011	2012	2013	2014	2	015 LT	CAGR
North America API Sales								
Oxycodone	\$ 61	\$ 86	\$ 82	\$ 93	\$ 94	\$	94	
Hydrocodone	36	40	41	34	52		38	
Morphine Sulfate	16	15	19	18	20		20	
Codeine Phosphate	9	13	10	11	13		16	
Buprenorphine HCl	1	3	4	4	6		11	
Hydromoprhone	2	3	7	6	9		7	
Oxymorphone	-	-	1	2	4		7	
Other	15	11	11	14	13		19	
Total N.A. API Sales	\$ 140	\$ 171	\$ 174	\$ 182	\$ 210	\$	212	8.6%
Growth vs Previous Yr	0.1%	22.2%	1.4%	5.1%	15.2%		1.0%	
ROW API Sales								
Codeine Phosphate	\$ 7	\$ 11	\$ 11	\$ 4	\$ 5	\$	5	
Buprenorphine Base	14	16	14	12	14		15	
Other	3	9	10	9	6		12	
Total ROW API Sales	\$ 24	\$ 36	\$ 35	\$ 25	\$ 25	\$	32	6.0%
Growth vs Previous Yr	14.3%	51.7%	-4.1%	-28.4%	1.5%		26.6%	
Narcotic Raw Material Sales								
Narcotic Raw Material	\$ 25	\$ 33	\$ 24	\$ 24	\$ 22	\$	16	
White Seed	13	17	19	19	-		-	
Total Narcotic Raw Material	\$ 38	\$ 50	\$ 43	\$ 43	\$ 22	\$	16	-16.1%
Growth vs Previous Yr	42.2%	31.4%	-14.4%	-1.4%	-47.2%		-28.8%	
Total Narcotic Sales	\$ 202	\$ 258	\$ 252	\$ 250	\$ 258	\$	260	5.1%
Growth vs Previous Yr	7.7%	27.4%	-2.5%	-0.7%	3.2%		0.9%	
Total Core Sales (Exclude NRM & Seed)	\$ 164	\$ 208	\$ 208	\$ 207	\$ 235	\$	244	8.3%
Growth vs Previous Yr	2.5%	26.5%	0.4%	-0.5%	13.5%		3.7%	

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# Detail 2: Products to J&J Affiliates (Kilograms, Un-Audited)



Affiliates sales are ~8% by volume of total sales.

Total Volume for 2015:

- ~177,000kg to 3<sup>rd</sup> Parties (no J&J)
- ~15,000kg to Affiliates and Future 3<sup>rd</sup> Party

### Volume (Kg) to J&J Affiliates → Future Trade Sales

Total Volume (kg)	3,621	10,692	21,483	22,011	15,598	15,093
Fentanyl				4	13	5
Tapentadol HCl	0	7,198	11,692	11,903	6,133	7,318
Hydromorphone HCl	621	519	617	671	522	592
Codeine Phosphate	3,000	2,975	9,174	9,433	8,930	7,178
	2010	2011	2012	2013	2014	2015 LT

Note: Historical sales revenue shown elsewhere do not reflect affiliate sales.

# Detail 3: Inventory By Product and Region (\$mm, Un-Audited)



	2014		
Noramco US Inventory	ctual		
Thebaine	\$ 17.1		
Oxycodone	\$ 15.1		
Morphine Sulfate	\$ 11.3		
Hydrocodone	\$ 10.7		
Buprenorphine	\$ 8.1		
Codeine Phosphate	\$ 7.0		
Oxymorphone	\$ 4.2		
Hydromorphone	\$ 3.2		
Other	\$ 5.7		
Total Noramco US Inventory	\$ 82.5		
Tasmanian Alkaloids Inventory			
Narcotic Raw Material	\$ 56.0	п	was a sample of the land of the standard of the same o
Buprenorphine	\$ 7.1	Consumer and the second	uprenorphine held per safety stock clause in
Total Tasmania Alk Inventory	\$ 63.0	C	ontract. Will be depleted in 2017
Schaffhausen/CMO Inventory			
Buprenorphine	\$ 25.1		
Codeine Phosphate	\$ 13.6	- In	cludes build for new products launching
Noroxymorphone	\$ 11.7		
Naloxone	\$ 11.3		
Naltrexone	\$ 4.3	E	cludes duplicate inventory at CMO
Methylnaltrexone	\$ 1.2	d	ue to Cilag site exit
Other	\$ 8.1		
Total Schaffhausen/CMO Inventory	\$ 75.2		
Geel Inventory			
Buprenorphine	\$ 2.7		
Total Geel Inventory	\$ 2.7		
Total 2014 Inventory	\$ 223.4		

Case: 1:17-md-02804-DAP Doc #: 2389-1 Filed: 08/14/19 85 of 97. PageID #: 393068 Detail 4: SG&A Overview

# Detail 4: SG&A Overview (\$mm, Un-audited)



Currency: \$USD Million

SG&A Overview	2	013	201	<b>L</b> 4	2015	LT
- Selling & Marketing		5		5		5
- Distribution		2		2		2
- Regulatory Affairs		1		1		1
- Legal		5		3		2
- Admin		4		4		4
Total SG&A	\$	17	\$	15	\$	14
Out of Ordinary Expense						
- PF Legal Expenses		(4)		(2)		(1)
Total Adjusted SG&A	\$	13	\$	13	\$	13

## Detail 5: Improvements in Profitability



### Oxycodone API ("OXY 3")

If all volume were OXY 3 in 2015 then GP would improve from 59% to 63%.

#### From 2013 to 2015:

- Conversion efficiency increased by 10%
- Overall right-first-time in production increased by 5%
- Plant occupancy reduced by 25%

#### Tasman Codeine API

If all volume were Tasman in 2015 then GP would improve from -9% to +33%.

#### From 2013 to 2015:

- Reduced manufacturing steps by 60%
- Eliminated reliance on Turkey
- Leverages Tasmanian Alkaloids

## Detail 6: API Transfer for Transition Services Agreement



DRAFT, Subject to Change	20	17	201	8	20	19	2020	2021	2022 2023		2024
Athone Coordin Dradusts	H1	H2	H1	<del>1</del> 2	H1	H2	H1 H2	H1 H2	H1 H2	H1 H2	H1 F
Athens, Georgia Products	_										
Hydromorphone HCl (Athens to Wilmington)		Te	ch Tra	nsf	er		Custo	mer Trans	itions		
Buprenorphine Base and HCl (Athens to CMO)		Te	ch Tra	nsf	er		C	ustomer		<b>▶</b> 1S	
Tapentadol (Athens to CMO)	Tech Transfer Customer Transitions										
Methylphenidate 1 Step (Athens to Wilmington)	Te	ech Tr	ansfe	100	Customer Transitions						
Hydrocodone Intermediates (Complete in Wilmington)	Customer Transitions										
Fentanyl API (B6 to CMO or buy)		Te	ch Tra	nsf	er		Cust	omer Trai	-> nsitions		
Geel, Belgium Products											
Buprenorphine Base (Geel to CMO, In Progress)					- C	usto	mer Trans	> itions			
Buprenorphine HCl (Geel to CMO)	Customer Transitions										
Schauffhausen Switzerland Products											
Dronabinol (Schaffhausen to CMO, In-progress)		Te	ch Tra	nsf	er		Cust	omer Trai	-> nsitic		
<u>Legend:</u> Buyer: Transfer, Validate, and Stability											

Buyer: Samples Available of Validated Filed API

Customer: Validate, Stability, File

# Case: 1:17-md-02804-DAP Doc #: 2389-1 Filed: 08/14/19 88 of 97. PageID #: 393071 Detail 7: Strategic Volumes Projection Used for Capacity

n / 1		•	/ <del></del>	
Mod	el	ing	(Tons)	

	2017	2018	2019	2020	2021	2022
Oxycodone HCl API	54	55	56	58	59	60
Hydrocodone Bitrate API	32	33	34	35	36	38
Buprenorphine Base and HCl	1.9	2.0	2.3	2.6	2.9	3.2
Hydromorphone API (w/ J&J)	3.0	3.3	3.5	3.5	3.5	3.6
Oxymorphone HCl API	1.2	1.2	1.3	1.3	1.4	1.5
Tasman Codeine API Worldwide (w/ J&J)	58	64	66	77	76	76
Morphine Sulfate API	21	17	15	15	15	15
Methylphenidate HCl (excludes J&J)	5	6	8	10	11	11
Naloxone HCl API	3.3	3.8	4.8	4.8	4.8	4.8
Naltrexone Base and HCI API	1.5	2.0	2.9	3.9	4.5	5.0
Amphetamines API	1.5	4.9	6.6	9.9	12.3	12.0
Methylnaltrexone Bromide API	3.3	6.6	8.0	8.5	8.5	9.0
Noroxymorphone Intermediate	2.4	2.4	2.5	2.5	2.5	2.5
Other (Intermediates, Small Volume APIs)	13	12	10	8	8	8
Trade Sales of Narcotic Raw Material (CPS-T, C, O)	112	131	135	138	140	141

Please Note: These are strategic volume forecasts including Pipeline Products and are not a guarantee of future business.

## Detail 8: Headcount Summary by Site



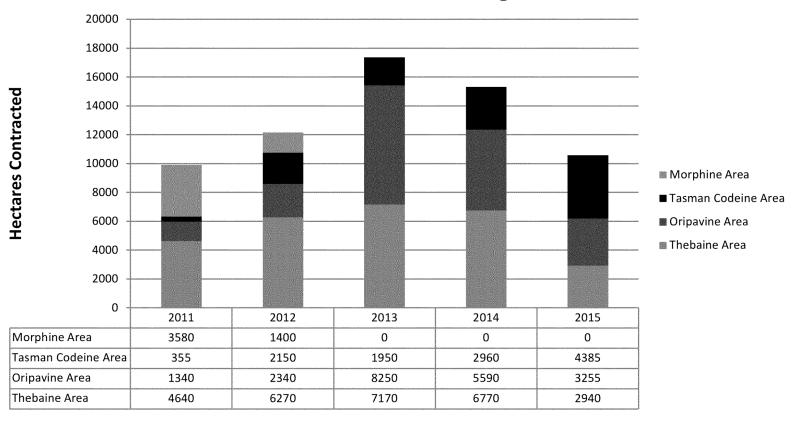
	Wilmington	Tasmania	Athens	Cilag	Shared	Total
	197	196	38	24	28	483
Manufacturing	139	131	1	1	7	279
Operations (Ops, Utilities, Shipping)	93	77				
Field Staff		17				
Maintenance and Tech Ops	27	20	1			
Engineering	5	8				
DEA + Security	4	5			1	
EHS	6	4			3	
Planning and Procurement	4			1	3	
Compliance	34	21	3	3	12	73
Quality	34	20				
Regulatory		1	3	3		
Scientific and Technical Support	4	28	32	15	o	79
Research & Innovation (Ag, Chemical, etc)		12	3	4		
Factory Support, Customer, and R&D	4	16	29	11		
Sales, Marketing, Customer Service	8	3	2	5	0	18
Administrative	11.5	13	0	0	9	33.5
Finance	7	6			2	
IT	2	4			3	
HR	1	2			1	
General Management	1	1			1	
Legal	0.5				2	

Please Note: **There will invariably be movement of headcount before closing**, additionally definitions being used are intended to give potential purchasers a relative idea of the proportions of personal in various locations and functions, **often personnel perform more than one function**.

## Detail 9: Tasmanian Alkaloids Growing Area



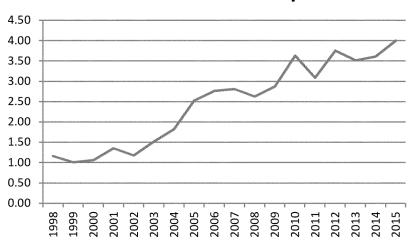
#### **Tasmanian Alkaloids Growing Area**



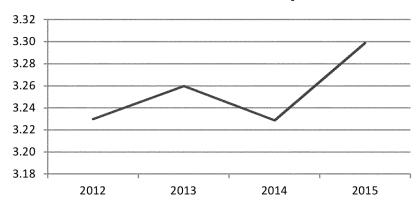
### Detail 10: Content of Alkaloids Overtime



### % Thebaine in Crop



#### % Codeine in Crop



Confidential

13

#### **Key Financial Metrics**

Currency: Million USD

	2013 Actual		2014 Actual		2015 LT
Net Income	\$	30	\$	37	\$ 30
Depreciation/Amortization	\$	16	\$	16	\$ 16
Capital Expenditures	\$	25	\$	23	\$ 19
Year End Inventory	\$	203	\$	223	\$ 229
AR Days		54		53	60*
AP Days		48		60	60*

#### Note:

<sup>- 2015</sup> AR Days of 60 reflects contractual payment terms for majority of customers.

<sup>- 2015</sup> AP Days of 60 is in-line with standard JNJ policy.



## **Groundhog – Supplemental Tax and Financial Information**



## **Important Notice**



Management believes the information provided in this presentation on the narcotic active pharmaceutical ingredients business and related manufacturing operations (the "Business") conducted by Noramco, Inc. ("Noramco") and Tasmanian Alkaloids Pty. Ltd. is accurate and reliable as of the date of this presentation unless another date is indicated. However, neither Noramco nor any of its affiliates in the Johnson & Johnson Family of Companies make any representation or warranty, express or implied, as to the accuracy or completeness of such information. Only those agreements, representations and warranties contained in a definitive written purchase agreement between Noramco and the successful bidder shall have any legal effect. Prospective purchasers are expected to conduct their own due diligence investigation and analysis, and not rely on the information and description of the Business provided herein. In addition, this presentation contains forward-looking statements and information. Neither Noramco nor its affiliates make any representation or warranty, express or implied, as to the accuracy or completeness of such forward-looking statements and information in this presentation. The audience should not rely upon any forward-looking statement or information in this presentation because Noramco and its affiliates give no assurance such statements or information will be realized. Each potential purchaser is expected by Noramco to do its own analysis as to the future prospects of the Business.

## **Supplemental Content**



- Detail 1: Additional Tax Information Tax Step Up
- Detail 2: Finance Schedule Cash Flow Reconciliation

## **Detail 1: Additional Tax Information - Tax Step Up**



- Johnson & Johnson intends that the buyer join it in executing a Section 338 (h)(10) election under the Internal Revenue Code in relation to the sale of the U.S. corporation included in the transaction.
- Additional information regarding the tax basis will be provided in the next round of the process.

# Detail 2: Finance Schedule - Cash Flow Reconciliation (\$mm, Un-audited)



	2013 A	ctual	2014 A	ctual	2015	LT
WWNF J&J Net Income	\$	30	\$	37	\$	30
Plus: Depreciation/Amortization		16		16		16
(Inc) / Dec - AR		16		(14)		(0)
(Inc) / Dec - Other Assets Liabilities		(2)		6		0
(Inc) / Dec - Inventory		(49)		(20)		(7)
Operating Cash Flow	\$	11	\$	25	\$	39
Capital Expenditures		(25)		(23)		(19)
Free Cash Flow	\$	(14)	\$	2	\$	20

#### **Notes:**

- Accounts Payable are included in Other Assets Liabilities.
- Free Cash Flow impacted by increase of inventory from 2013 2015
  - Inventory increase related to transition from JNJ manufacturing sites to contract manufacturing sites and introduction of new products.